2012 WL 2924483 (Md.App.) (Appellate Brief)
Maryland Court of Special Appeals.

Mafalda FUSCO, et al., Appellants,
v.
Kevin J. SHANNON, M.D., et al., Appellees.

No. 2819.
September Term, 2010.
May 18, 2012.

On appeal from the Circuit Court for Prince George's County (Before the Honorable Leo E. Green, Jr.)

Appellees' Brief

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*1 STATEMENT OF THE CASE

This appeal arises from a medical malpractice action filed against Kevin J. Shannon, M.D., Hematology-Oncology Consultants, (hereinafter Appellees or "Dr Shannon"), Walid Mufarrij, M.D., and Lawrence Shombert, M.D. based on medical care provided to then eighty-three-year-old (83) Anthony Fusco in 2003. Dr. Mufarrij was Mr. Fusco's urologist, directing treatment options for his prostate cancer. Dr. Shombert was Mr. Fusco's radiologic-oncologist and Dr. Shannon was Mr. Fusco's hematologic-oncologist. The allegations against all physicians sounded in lack of informed consent *only. No allegations of medical negligence* were waged against any of these providers.

Appellants identified two expert witnesses in an effort to support their lack of informed consent claims against the Appellees and other physicians: Dr. Al-Ibrahim, an infectious disease physician, and James Trovato, a pharmacist. Dr. Trovato's trial testimony was conducted via videotaped de bene esse deposition on November 30, 2009. [E.132-162]. Shortly thereafter, Appellees filed a Motion in Limine to Exclude James Travato's Testimony at Trial. [E.110 -178]. The basis for that Motion was essentially twofold: First, Dr. Trovato was a pharmacist, not a physician, and accordingly, was not qualified to offer opinions about what a physician was required to advise a patient to obtain informed consent. Second, Dr. Trovato's de bene esse testimony offered criticisms sounding in standard of care (i.e., whether it was appropriate to use Amifostine), not as to informed consent (whether the appropriate information about the risks, benefits and alternatives to ***2** Amifostine were provided to the patient). The trial court granted Appellees Motion in Limine and precluded Appellants from utilizing James Trovato's testimony at trial.

Appellees also filed a Renewed Motion for Summary Judgment on the basis that Appellants failed to adduce the requisite evidence to establish that the risk of Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis Syndrome (TENS) [1] was a material risk to the use of Amifostine requiring a physician to disclose this information for purposes of informed consent. Without such evidence, Appellees maintained that they were entitled to summary judgment on the lack of informed consent claim as a matter of law. The trial court denied Appellees Motion for Summary Judgment on December 21, 2010. [E.534]. Accordingly, this matter proceeded to trial before a jury from January 10 - January 19, 2011.

On January 19, 2011, the jury returned a verdict in favor of Appellees. [E.1713-1714]. Specifically, the jury unanimously concluded that a reasonable patient, having been informed of the material risks and complications associated with Amifostine would *not* have refused to consent to its use. [2] *Id.* Appellants filed ***3** a timely notice of appeal to this Court and Appellees filed a conditional Cross-Appeal, with the following question presented:

STATEMENT OF QUESTIONS PRESENTED ON APPEAL

Whether the trial court properly exercised its broad discretion in granting Appellees' Motion in Limine to preclude James Trovato, Pharm.D's testimony at trial.

Whether the trial court properly exercised its broad discretion in precluding the use of or reference to the drug package insert and FDA approval.

STATEMENT OF QUESTION PRESENTED ON CROSS-APPEAL

Whether the trial court erred in denying Appellees' Motion for Summary Judgment and/or whether the trial court erred in denying Appellees' Motions for Judgment given that Appellants' did not adduce evidence that Dr. Shannon failed to advise Mr. Fusco of "material risks" to Amifostine, either in discovery or in trial.

STATEMENT OF FACTS

A. Pertinent Medical Treatment

Appellee Dr. Shannon first saw the decedent, Mr. Fusco, on March 12, 2003. At that time, Mr. Fusco was approximately 83-years old and was in early stage localized prostate cancer, Tic with a Gleason score of 6. Mr. Fusco's prostate cancer had been diagnosed by a Dr. Kumar in 2001, and at that time Mr. Fusco opted for "watchful waiting." Apparently, it was Mr. Fusco's discomfort ***4** with this "watchful waiting" strategy that ultimately led him to discuss alternative avenues with Drs. Mufarrij and Shombert, his urologist and radiologic-oncologist, respectively.

According to Dr. Mufarrij's office note of February 21, 2003, Mr. Fusco and his family "did not feel comfortable with watchful waiting" and were therefore provided three options: 1) continue watchful waiting; 2) hormone therapy with radiation; or 3) hormone therapy without radiation. Mr. Fusco opted for the hormone therapy *with* radiation.

Co-defendant Dr. Shombert was Mr. Fusco's treating radiation-oncologist; after discussions with Mr. Fusco about radiation therapy, Dr. Shombert referred Mr. Fusco to Dr. Shannon at Hematology-Oncology Consultants, P.A., for additional discussions regarding a supplemental medication regimen commonly utilized for patients undergoing radiation; specifically, Amifostine therapy (also known as Ethyol). [E.1428]. During his visit with Dr. Shannon, Mr. Fusco was educated about how, in an effort to counter cancer, radiation also can collaterally attack non-cancerous elements of the body's immune system. [E.1413-15]. Thus, cancer patients are often be prescribed a "radiation-protectant" such as Amifostine, as a prophylactic against collateral damage to the body's healthy structures. [E.1419-20]. During this discussion, in which Dr. Shannon utilized explanatory diagrams and photographs, Mr. Fusco was advised of the potential side effects of the protectant medications. [E.1444-45]. Dr. Shannon discussed with the patient that Amifostine needed to be given every day prior to radiation, ***5** [E.1424-25], and advised that the material risks to this medication included the nausea, lowering of blood pressure, and dermatologic reactions. [E.1438-39, 1445] [Apx.000001-000002]

Ultimately, Mr. Fusco underwent approximately 23 treatments with Amifostine between April 15 and May 16, 2003. During these treatments, Mr. Fusco was seen by Appellees and Dr. Shombert. Following a course of Amifostine treatment on May 16, 2003, Mr. Fusco presented to Doctors Hospital with an acute rash on May 17, 2003. Dr. Shannon examined Mr. Fusco at the hospital and believed that the decedent's acute rash may have been caused by Amifostine. Accordingly, he recommended that antihistamines and other various medications be given to counteract the allergic reaction.

Ultimately, Mr. Fusco was transferred to Bayview on May 20, 2003, for treatment of his dermatologic problems, which advanced to a rare condition known as Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (TENS). Mr. Fusco recovered from TENS and was discharged to Magnolia Nursing Home in August, 2003. Although Mr. Fusco's dermatologic problems resolved, [E.1327, 1331], Mr. Fusco was admitted to Doctors Hospital with respiratory problems in late October, 2003.

Despite efforts to improve Mr. Fusco's respiratory distress over the ensuing weeks, he developed and succumbed to a stroke on December 4, 2003. [E.1330]. No autopsy was performed on Mr. Fusco, nor requested by Appellants.

***6 B. Appellants' Lack of Informed Consent Claim**

Appellants filed this lawsuit against and Appellees (and other healthcare providers) alleging that Appellees failed to appropriately advise Mr. Fusco of the material risks, benefits and alternatives to Amifostine in Mr. Fusco's cancer treatment regimen, and failed to obtain the requisite informed consent of Mr. Fusco.

The following is significant to this Court's evaluation of the issues on appeal, just as it was significant to the lower court: Appellants waged no complaints or causes of action sounding in medical negligence against Dr. Shannon. Meaning to say, there were no allegations that Dr. Shannon's (or Dr. Shombert's) recommendation to use Amifostine in Mr. Fusco's treatment plan was inappropriate or a breach in the standard of care. Appellants' claims were limited to lack of informed consent only.

C. Appellants' Pharmacists' Testimony

As summarized above, Appellees identified two expert witnesses in this matter. An infectious disease expert, Dr. Mohamed Al-Ibrahim, was identified to testify as to issues of causation only. [E.85]. Specifically, Dr. Al-Ibrahim was identified to testify that the Amifostine taken in May 2003 caused Mr. Fusco's death from pneumonia approximately seven months later (and four months post-recovery from TENS). [E.86]. He provided no opinions as to lack of informed consent issues.

***7** Appellants also identified a pharmacist, [3] James Trovato, to testify as to "whether the use of Amifostine was appropriate in the care and treatment of Anthony Fusco." [E.86]. Similarly, Dr. Trovato's discovery deposition confirmed that his opinions were confined this belief that "the use of Amifostine for this patient, I feel is not justified or inappropriate." [E.402].

In lieu of appearing live at trial, Dr. Trovato's testimony was taken via de bene esse on November 30, 2009. At this de bene esse, both Dr. Trovato's qualifications to testify regarding a physician's informed consent process, as well as the substance of Dr. Trovato's opinions were challenged. Additionally, Appellees objected to Dr. Trovato's use of a package insert from another manufacturer of Amifostine, as well as reference to literature on clinical trials and FDA approval. A pertinent summary of his testimony is provided herein:

1. Dr. Trovato's (lack of) qualifications

Dr. Trovato is not a physician. [E.140]. He did not attend medical school. Rather, he received his doctorate in pharmacy. Dr. Trovato did not complete a Residency or Fellowship, like Dr. Shannon. [E.1391-92]. He is not board certified in Internal Medicine, like Dr. Shannon. [E.140][E.1391-92]. He did not take additional specialized training to become board-certified in Hematology, like Dr. Shannon. *Id.* He did not take additional specialized training to become board- ***8** certified in Oncology, like Dr. Shannon. *Id.*

Dr. Trovato is not licensed to practice medicine. [E.139]. He doesn't have privileges at any hospital, he cannot admit patients to the hospital, and *he cannot prescribe medications.* [E.140]. He has never sat down with a patient and written a prescription for medication at any time. [E.143]. Dr. Trovato does not diagnose patients, and the ultimate therapy determined for a patient is up to the medical physician. [E.143]. He conceded that his "involvement" with patients is solely one of collaborating with the physician medical doctor about medication options. [E.143]. He has never used and never administered an injection to a patient, and certainly never used or administered Amifostine. [E.143].

Dr. Trovato does not have a separate office where he actual sees patients in an office setting for purposes of rendering care and treatment and management. [E.156]. Most notably, he's **never obtained a patient's consent to treatment, and in particular, to the use of Amifostine.** [E.157, 160]. Dr. Trovato has never been in attendance at any session or meeting between a medical doctor, like Dr. Shannon, where that medical doctor has sought to obtain a consent from a patient regarding the use of Amifostine. [E.157]. In fact - he has never, in his career, been asked for his opinion as to whether Amifostine was appropriate for the use in

any patient. [E.158]. Dr. Trovato conceded that he did not know the potential benefits to the drug in a patient like Mr. Fusco. [E.1601. Most notably, when asked whether he understood the term "material risks" - Dr. Trovato responded that he did not. [E.143].

***9 2. Dr. Trovato's opinions were unrelated to informed consent.**

Notwithstanding his lack of qualifications to testify as to the failure of Dr. Shannon to obtain informed consent, the substance of Dr. Trovato's testimony (both in deposition and in his videotaped trial testimony) was irrelevant given that Dr. Trovato's opinions centered on the **inappropriate use of Amifostine rather than the insufficient information provided to the patient** about Amifostine.

Notably, Dr. Trovato expressed the purpose of his testimony at the inception of his de bene esse deposition: "my understanding is that I'm here to testify as to the appropriate use of amifostine in this case." [E.139] This understanding was the same understanding that he provided in his discovery deposition: " ""My opinions in terms of the use of Amifostine for this patient, I feel is not justified or inappropriate. Again, Amifostine in terms of how its being used in this patient's case, this specific patient's case. That's my opinion." [E.402]. Accordingly, nothing changed over the course of discovery vis-a-vis Dr. Trovato's opinions: his criticisms related to the use of the drug as opposed to the information conveyed about the drug.

During the course of the video-taped trial testimony, Appellants' counsel spent an inordinate amount of time on the FDA approval process relating to drugs, in general, as well as how clinical trials are utilized in the drug approval process. [E. 147-151]. Additionally, Dr. Trovato was asked about certain clinical trials for the radiation-protectant drugs, in terms of their relation to prostate cancer. [E.152-53]. Dr. Trovato then was merely taken through the "package insert" for ***10** Amifostine (over objections based on form, foundation, relevance and hearsay), and asked about the "hypersensitivities" to the drug.

The only questions asked on direct examination, to a reasonable degree of medical probability, pertained to Dr. Trovato's opinions on the **appropriateness of the use** of the drug Amifostine in a patient with prostate cancer.

Q: In this particular case, the radiation for prostate cancer. Would that be a logically - do you have an opinion within reasonable medical certainty likes [sic] amifostine in a patient if you chose the use for prostate cancer?

Mr. McManus: Objection.

Mr. Farley: Objection.

Mr. Goodson: Objection. Form and foundation.

A: That would not be logical. Typically the radiation therapy is directed to the pelvic area for prostate cancer, so its not going to affect the glands, if that what you're asking.

[E.151, Tr. Pg. 67].

Q: Do you have an opinion within a reasonable medical certainty or probability as to whether or not it was appropriate to administer amifostine for - while being given radiation treatment for prostate cancer?

Mr. Farley: Objection. Form, foundation, relevancy.

Mr. Goodson: Same objection.

A: I do have an opinion

Q: What is your opinion?

A: My opinion is that amifostine was **inappropriately used or should not have been used** for the reason of a patient getting radiation therapy for prostate cancer.

[E.151, Tr. Pg.69].

***11** In fact, he clarified that his earlier testimony pertaining to the clinical trials and the manufacturer's package insert formed the *basis* for his opinions that Amifostine **should not have been used** in this case. [E. 151-151, Tr. Pgs. 69-70], E.155].

The only testimony remotely pertaining to "informed consent" occurred when Dr. Trovato was asked *where* the patient gets information to make a decision about treatment. His response: "it can come from other health care professionals. There's various sources. But generally, for the most part, health care professionals will communicate to the patient the risk/benefits of a particular treatment, and then again, it's the patient's decision..." [E.152].

In short, Dr. Trovato provided no opinions as to what information, specifically, was required to be disclosed by Dr. Shannon that would constitute "material risks, benefits, and alternatives" to this drug.

To the extent this Court believes there to be any ambiguity on this issue, on cross-examination, Dr. Trovato emphasized, again, that his opinions pertained to the decision to use Amifostine for Mr. Fusco: "I did not come across literature that was pertinent in this case,... **the case being, the use of amifostine** to prevent cystitis proctitis in prostate cancer patients." [E.156]. Dr. Trovato readily reiterated that his opinion was that "**the use of amifostine in this situation was inappropriate.**" [E.158]. And furthermore, that the bases for his opinion that the use was inappropriate were that the drug was not FDA approved for prostate cancer patients, there was a lack of clinical trials for use in prostate cancer ***12** patients, and there was a lack of data for use in **elderly** patients (and thus, the precautions noted in the package insert). [E.158-59]. In short, Dr. Trovato verified on cross-examination that the entirety of his opinions pertained to the alleged inappropriate use of Amifostine and the bases in support thereof. Id. Dr. Trovato reiterated again that his ultimate opinion in this case was that Amifostine should not have been used. [E.160]. It was wrong to use Amifostine. [E.161]. Period.

It was only on redirect, that Appellants' counsel attempted to ask a question about what a patient should be advised (in a leading manner, no less) :

Q: If a patient is going through a clinical trial, should they be advised of the risks as well as the benefit?

Mr. Goodson: Objection.

Mr. Farley: Objection, beyond the scope of direct, form, foundation and relevancy.

A: Yes.

[E.162]. Even that inappropriate question, which was well-beyond the scope of direct or cross-examination, failed to elicit the necessary testimony as to the *material* risks that Dr. Shannon was obligated to advise Mr. Fusco.

Accordingly, the entirety of Dr. Trovato's de bene esse pertained to his opinion about the misuse of Amifostine. Meaning to say, Dr. Trovato's opinion was that the use of Amifostine was improper, or negligent. He offered no opinions that information that Dr. Shannon provided Mr. Fusco was insufficient information on which informed consent could be given by the patient.

***13 D. Judge's Ruling on Motion in Limine**

For these reasons, Appellees filed a Motion in Limine seeking to preclude the jury from hearing the irrelevant and otherwise objectionable testimony of Dr. Trovato.

On December 21, 2010, Judge Green heard argument on Appellees' Motion. The trial court correctly noted that Dr. Trovato's testimony failed to discuss informed consent, i.e., **"where is his testimony about informed consent**?" [E.550]. When Appellant's counsel pointed to the one page where Dr. Trovato discussed the common risks to the drug (which he essentially listed from the package insert), the trial judge astutely noted "[t]hat's talking about the risks. Not talking about material risks." [E.550](emphasis added). The court expounded that Dr. Trovato "doesn't testify as to what the material risks are. And that gets to the meat of it. There are risks in everything. I walk out here and walk down the step, I could trip on my robe. That's a risk, but its not a material risk." *Id.*

The lower court's distinction is significant when considering a lack of informed consent claim. The standard by which a physician is judged is not his failure to discuss every risk, but rather, his failure to discuss the "material risks, benefits, and alternatives" to the procedure. *See McQuitty v. Spangler*, 410 Md. 1, 12, 976 A.2d 1020, 1032 (2009).

Additional grounds were raised in support of precluding Dr. Trovato's testimony. In fact, the trial acknowledged that there were additional problems with Dr. Trovato's testimony, above and beyond the fact that the substance did not ***14** appear to relate to informed consent, (i.e., the substance of his testimony was only the first hurdle). [E.547-48]. For example, to support his opinion, Dr. Trovato relied heavily upon a package insert from Amifostine. The insert on which he relied, however, post-dated 2003 (the year of the incident in this case) and was an insert from a different manufacturer (Immunex) than the one utilized in 2003 (Medimune). [E. 160, E.553] Accordingly, Dr. Trovato's reference to "risks" that were espoused in the package insert was inappropriate given that it was created by a different manufacturer and post-dated the use of the drug in this case.

Regardless, after hearing argument on Appellees' motion in limine, the trial court ruled as follows:

The Court grants the motion for the following reasons. That's not to say I would exclude him at trial, okay. But the testimony as given gives **a great indifference to relevance to the issue at hand.** That is informed consent. Secondly, he doesn't testify as to the standard of an expert in an informed consent case. Third, there's no testimony in the transcript that is consistent with these standards. Four, his testimony is more in line, in the totality when you take out all of the objections and everything else, **testimony is more in line with negligence than that of informed consent.** And as a result of this, it is more prejudicial than probative to the issue at hand. Lastly, but not - and I use it as a last situation, is that he's a pharmacist, **not a medical doctor. And he's not testifying with the five standards that are found in Sard.** Information that must be communicated. The nature of the ailment. The nature of the risk of a treatment. The probability of success. The frequency of occurrence of the risk. He never gets into that. Is it a risk? Yes. But he doesn't give it and he doesn't testify as to what the available alternatives to the treatment are. He testifies as to the risk but he doesn't give a whole thing." [E.558-59].

At a subsequent hearing related to Dr. Trovato's testimony, the lower court revisited the grounds for his ruling to preclude the de bene esse, and reiterated as ***15** follows:

"... first and foremost, we must remember that this is a trial that does not have a negligence count. It has a simple count of a lack of informed consent. This is important in the Court's consideration....

... I adopt what I said earlier and will add to it today as for my reasons... I looked at the question of what the status of Dr. Trovato was... and he quite frankly, **he's a pharmacist.** He's not a medical doctor. And as such, when you look and you review what, under Maryland Rule 5-701 and 5-702, what an expert is. In this matter, it is not just the sole issue of what medicines were used. But it is a sole and complete treatment plan that is before this Court. It is not just that sole issue that we have before us. And remember that the pharmacist is dealing only with a small part of the treatment plan, the medications. And that is where his expertise is. It's not in the complete treatment plan. **So he only deals with the medications.**

... informed consent... is not just the medications, but the entire treatment. And as such, a **pharmacist does not, in the Court's opinion, have the ability to give the full demarcation as to what is involved in informed consent.**

Quite frankly, he's never given an informed consent. He's not trained in informed consent. And he, quite frankly, he is very limited in what he does with patients. And the final call is not his. It is always the doctor. That's the way the medical system is set up."

[E.575-76](emphasis added).

The court acknowledged that Dr. Trovato was well-qualified in the area of pharmacy, but correctly noted that "this is a different area." [E.579]. Accordingly, it wasn't his lack of qualifications, per se, but his lack of qualifications as it related to the "nature of this case." [E.580]. In short, "informed consent is not in his field." [E.580].

In support of his ruling, the trial court went on to discuss, at length, the ***16** standards outlined in *Sard v. Hardy*, 281 Md. 432 (1977), *Mahler v. Johns Hopkins Hospital, Inc.*, 170 Md. App. 293 (2006) and *University of Maryland Medical System v. Waldt*, 411 Md.207 (2009), and maintained that "these cases are controlling in [the court's] decision to disallow Dr. Trovato to testify." [E.578].

Finally, the court reiterated, again, that Dr. Trovato's testimony "is more in line, after I read it, in negligence rather than informed consent," and thus, it would not be probative to the trier of fact. [E.578]. Judge Glenn believed that "it would confuse and disenchant the jury in their ability to determine what the doctrine of informed consent really is, if they listen to this sole expert on pharmacy [sic]." [E.578]. Furthermore, his testimony did not provide an understanding as "to what has to be done with this patient," which was "another reason why I'm disallowing him." [E.578].

E. Appellees' Motion for Summary Judgment and Motions for Judgment.

Prior to trial, Dr. Shannon moved for summary judgment on the grounds that Appellants did not produce any (qualified) expert to testify that Dr. Shannon failed to advise Mr. Fusco of the material risks, benefits and alternatives to Amifostine so as to constitute proper informed consent. To be clear: Appellees have maintained all along that Dr. Trovato, as a pharmacist, did not possess the requisite experience or training to be qualified to testify as to the informed consent process that occurred between a physician and a patient. Thus, even prior to the lower court's determination to preclude the de bene esse testimony of Dr. Trovato, ***17** Appellees contested his ability to offer such testimony. [E.590]. Dr. Shannon maintained that under Sard, and its progeny, expert testimony is required to establish the material risks - and "material" is defined as "what a physician knows or should have known would be significant to a patient." *University of Maryland Medical System v. Waldt*, 411 Md. 207, 232, 983 A.2d 112, 127 (2009); *Sard v. Hardy*, 281 Md. 432, 443-444, 379 A.2d 1014, 1022 (1977). Nevertheless, the Court believed that "at this stage of the proceedings" there was some dispute as to material fact, and thus, he denied the Appellees' Motion for Summary Judgment. [E.533]. The matter proceeded to trial.

At the close of Appellants' case, and again at the close of the evidence, Appellees moved for judgment on several grounds. [E.1259, 1543]. Appellees maintained that Appellants did not establish a *prima facie* case of lack of informed consent, in that there was no evidence that Dr. Shannon failed to advise the patient of the material risks to the procedure. [E.1260-61]. Maryland law required some testimony that Dr. Shannon failed to convey a material risk to the patient; Appellants adduced no such evidence, either in their case-in-chief, or over the course of the trial. [E.1264-1267]. Given that the definition of "material" is what a "physician knows or should know would be significant to a reasonable person in making a decision," Appellees maintained that Appellants had to produce testimony in their case-in-chief that SJS/TENS was the type of risk that Dr. Shannon should have known about, and should have relayed to Mr. Fusco when providing informed consent. *Id.* The trial court denied Appellee's Motions for ***18** Judgment [E.1275, 1554], and the matter was tendered to the jury for deliberations. The jury returned a verdict in favor of Appellees on January 19, 2011. [E.1713-1714].

ARGUMENT AS TO ISSUES ON APPEAL

A. Standard of Review

Evidentiary rulings, particularly those hinging on relevance, are entrusted to the wide discretion of the trial judge. See *Merzbacher v. State*, 346 Md. 391, 404, 697 A.2d 432, 439 (1997). An appellate court will not second-guess such a decision absent a clear **abuse** of the trial court's discretion. *See Smallwood v. Bradford*, 352 Md. 8, 27, 720 A.2d 586, 595 (1998); *North River Ins. Co. v. Mayor and City Council of Baltimore*, 343 Md. 34, 89-90, 680 A.2d 480, 508 (1996); *Armstead v. State*, 342 Md. 38, 66, 673 A.2d 221, 235 (1996).

In addition, to prevail on appeal when contesting a court's evidentiary ruling, the aggrieved party must establish that the error "was both manifestly wrong and substantially injurious." See Beahm v. Shortall, 279 Md. 321, 331, 368 A.2d 1005, 1011 (1977)(quoting Rotwein v. Bogart, 227 Md. 434, 437, 177 A.2d 258, 260 (1962))(emphasis added); See also Benik v. Hatcher, 358 Md. 507, 537, 750 A.2d 10, 26 (2000)("It is well settled that a civil judgement will not be reversed unless the complaining party shows both error and prejudice."). Meaning, error by the lower court alone will not suffice. Substantial injury must also be established. Unless the aggrieved party establishes substantial injury, there the verdict will stand. See ***19** Harris v. Harris, 310 Md. 310, 319, 529 A.2d 356, 360 (1987); McQuay v. Schertle, 126 Md. App. 556, 587, 730 A.2d 714, 730-31 (1999)(quoting Beahm, supra, 279 Md. at 331, 368 A.2d at 1011).

The evidentiary rulings made by the trial court below were neither manifestly wrong nor substantially injurious. As a result, the court's rulings should be upheld and the judgment in favor of Dr. Shannon should be affirmed.

B. The Trial Court's Preclusion OF Dr. Trovato's Trial Testimony WAS Proper

As was explained above, Dr. Trovatos trial testimony was effectively given in this case, by way of *de bene esse* deposition. Accordingly, the trial court had the benefit of knowing the precise nature of Dr. Trovato's testimony in considering whether to preclude that testimony. In making its ruling, however, the trial court also considered the discovery deposition of Dr. Trovato and the "proffer" drafted by Appellants' counsel after they recognized the gaping holes in Dr. Trovato's discovery and trial testimony. Notably, Appellants' counsel in Brief to this Court relies almost exclusively on the proffer they drafted as opposed to the actual testimony by Dr. Trovato. There is good reason for this: by doing so, they are able to employ revisionist history and/or wishful thinking, as it related to Dr. Trovato's opinions. Dr. Trovato's videotaped trial testimony, as well as the opinions he gave in deposition, belie those attempts. Regardless, it is significant that even the "proffer" produced by counsel doesn't make out a *prima facie* case of informed consent. Nowhere does it state that the material risks to Amifostine, which Dr. Shannon was obligated to disclose to Mr. Fusco in order to obtain ***20** informed consent are "X". To the extent that this Court reads the proffer otherwise, then Appellants have another insurmountable hurdle: given that Dr. Trovato had never before testified that Dr. Shannon failed to obtain informed consent by failing to disclose certain material risks, any such opinions would constitute "new opinions" not previously disclosed in discovery. [4]

1. The substance of Dr. Trovato's opinions sounded in negligence, not lack of informed consent - and thus, were not relevant and/or the prejudical effect outweighed any probative value.

It is incontrovertible that Dr. Trovato's testimony in deposition, as well as his videotaped trial testimony, revealed his opinions to be that it was inappropriate for Dr. Shannon to utilize Amifostine in Mr. Fusco given his age and given that his cancer involved the prostate, as opposed to kidney, bladder and neck cancer. These opinions clearly sound in negligence (malpractice) as opposed to lack of informed consent.

Medical malpractice and lack of informed consent are two distinct causes of action in Maryland. The Court of Appeals in *McQuitty v. Spangler, supra,* expressly stated that "[b]reach of informed consent and medical malpractice claims both sound in negligence, but are separate, disparate theories of liability." *McQuitty,* 410 Md. at 18, 976 A.2d at 1030. The Court of Appeals then cited several cases in which that distinction was not only upheld but illuminated: *Landon v. Zorn,* 389 Md. 206, 230, 884 A.2d 142, 156 (2005)(upholding a trial ***21** judge's decision to instruct the jury on a medical malpractice theory of liability, but not on an informed consent theory); *Reed v. Campagnolo,* 332 Md. 226, 240-41, 630 A.2d 1145, 1152-53 (1993)(holding that a failure to recommend a diagnostic procedure is properly an allegation of medical malpractice, not one of breach of informed consent); *Faya v. Almaraz,* 329 Md. 435, 447-51, 620 A.2d 327, 333-35 (1993) (holding that patients stated a proper cause of action when they alleged that the physician breached a duty to obtain their informed consent by failing to inform them that he was infected with the AIDS virus before operating, without alleging that physician breached the standard of care in performing the procedure); *see also Zeller v. Greater Baltimore Medical Center,* 67 Md. App. 75, 81-82, 506 A.2d 646, 650 (1986) ("The rendering of medical services absent informed consent, if pled properly, constitutes a separate and new count of negligence.").

The Court explained the distinction between these claims as follows: "In a count alleging medical malpractice, a patient asserts that a healthcare provider breached a duty to exercise ordinary medical care and skill based upon the standard of care in the profession,... while in a **breach of informed consent** count, a patient complains that a healthcare provider breached a duty to obtain effective **consent to a treatment or procedure** by failing to divulge information that would be material to his/her decision about whether to submit to, or to continue with, that treatment or procedure." McQuitty, 410 Md. at 18-19, 976 A.2d at 1030 (internal citations and quotations omitted)(emphasis added). 21

***22** The Court of Appeals explained that "unlike the traditional action of negligence, a claim for lack of informed consent focuses not on the level of skill exercised in the performance of the procedure itself but **on the adequacy of the explanation given by the physician in obtaining the patient's consent."** *Dingle v. Belin,* 358 Md. 354, 369-70, 749 A.2d 157, 165 (emphasis added).

As hard as Appellant's try to fit a square peg into a round hole, Dr. Trovato's testimony clearly and unequivocally sounded in negligence - and not lack of informed consent.
"My opinions in terms of the **use** of Amifostine for this patient, I feel is not justified or inappropriate. Again, Amifostine in terms of **how its being used** in this patient's case, this specific patient's case. That's my opinion." [E.402] (discovery deposition)

"Amifostine-Ethyol was inappropriate in this patient." [E.402] (discovery deposition)

Dr. Trovato agrees that his opinion is that the use of Amifostine was not justified or appropriate. [E.403] (discovery deposition)

"I think my concern is there is no evidence to support its efficacy for its use in this case." [E.405] (discovery deposition)

"there is no evidence to support its use, its efficacy. There is a known toxicity. Again, when we look at the risk-benefit, I guess I don't see a benefit to the drug." [E.407] (discovery deposition)

"my understanding is that I'm here to testify as to the appropriate **use** of amifostine in this case." [E.139](*de bene esse*)

"My opinion is that amifostine was **inappropriately used or should not have been used** for the reason of a patient getting radiation therapy for prostate cancer." [E. 151, Tr. Pg. 69] (de bene esse).

***23** "I did not come across literature that was pertinent in this case,... **the case being, the use of amifostine** to prevent cystitis proctitis in prostate cancer patients." [E.156] (*de bene esse*).

Dr. Trovato readily reiterated that his opinion was that "**the use of amifostine in this situation was inappropriate."** [E.158] (*de bene esse*).

Dr. Trovato reiterated that his ultimate opinion in this case was that Amifostine **should not have been used.** [E.160] (*de bene esse*).

Dr. Trovato believed that it was *wrong to use* Amifostine. [E.161] *(de bene esse).*

In both his discovery deposition and videotaped trial testimony, Dr. Trovato further explained that the basis for his opinion that that amifostine **should not have been used** in this case included: the lack of FDA approval in prostate cancer patients specifically, the limited clinical trials on prostate cancer patients, and the limited studies in the **elderly** (as espoused in the manufacturer package insert). [E.151-51, (Tr. Pgs. 69-70), E.155, E.158-59, E.403-405]. Accordingly, all of Dr. Trovato's opinions adduced in discovery pertained to the alleged misuse of Amifostine, and the bases thereof. Meaning to say, Dr. Trovato's opinion was that the use of Amifostine was improper, or negligent. He offered no testimony that Dr. Shannon provided Mr. Fusco with insufficient information on which informed consent could be given by the patient.

To the extent that Dr. Trovato touched on the common side effects or potential adverse reactions to Amifostine, those opinions similarly do not carry the ball for Appellants. The lower court correctly noted: "your guy [Dr. Trovato] ***24** doesn't testify as to what the material risks are. And that gets to the meat of it. There are risks in everything. I walk out here and walk down the step, I could trip on my robe. That's a risk, but its not a material risk." [E.550]. As the lower court stated, it is not that risks exist that is relevant in an informed consent case, the pertinent question is whether those risks were material to the treatment proposed and thus warranted disclosure by Appellants. *Id.* The fact that Dr. Trovato can pull a (post-dated) package insert from a (different) manufacturer of Amifostine and cite the myriad of possible adverse reactions does not mean that Dr. Shannon had a duty to disclose each and everyone of those risks. Dr. Trovato never identified which risks were material to an informed consent discussion with a patient; Dr. Trovato never testified that Dr. Shannon needed to disclose risk "x" or risk "y" to constitute informed consent. Appellants never adduced that testimony in discovery; (nor did they adduce that testimony at trial).

Accordingly, the trial court properly concluded that the substance of Dr. Trovato's testimony was not relevant to the cause of action at hand, i.e., lack of informed consent. [E.558-59, E.575-76]. Additionally, Dr. Trovato's opinions would be confusing to the jury and otherwise prejudicial if they were to be permitted. *Id.*

Evidence that is not relevant is not admissible. See Md. RULE 5-402. Furthermore, even if relevant, when the probative value of that evidence is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, the evidence may be excluded. See ***25** Md. Rule 5-403. A ruling on relevance of evidence is quintessentially within the wide discretion of the trial court. *See Phoenix Services, Ltd. v. Johns Hopkins Hospital,* 167 Md. App. 327, 892 A.2d 1185 (2006). Appellate courts will not disturb a trial court's decision to admit or exclude evidence absent an **abuse** of discretion. *See Ruffin Hotel Corp. of Maryland, Inc. v. Gasper,* 418 Md. 594, 619, 17 A.3d 676, 690 (2011). Appellate courts utilize a "clearly erroneous" standard of review in assessing the lower court's ruling as to whether or not the evidence has "probative value." *Id.* at 620.

The trial court's determination below was well-considered and soundly analyzed. After reviewing the pleadings, conducting two separate hearings on the matter, reading the deposition testimony of Dr. Trovato, the de bene esse of Dr. Trovato, the proffer by Appellants' counsel and multiple cases from our appellate courts, Judge Green found that Dr. Trovato's testimony gave **"great indifference to relevance to the issue at hand.** That is informed consent." [E.558-59]. Meaning to say, Dr. Trovato's **"testimony is more in line with negligence than that of informed consent."** *Id.* The trial court's finding in this regard was entirely appropriate; accordingly, the court did not **abuse** its discretion in precluding Dr. Trovato's testimony at trial. The court's ruling should be upheld and the judgment below affirmed.

2. Dr. Trovato lacked the requisite experience or qualifications to offer opinions as to informed consent.

In addition to the lower court's finding that the substance of Dr. Trovato's ***26** testimony was not probative to the issue at hand (and prejudicial), the lower court also found that Dr. Trovato lacked the necessary experience and training about informed consent processes between a physician and patients under Maryland Rule 5-702. Furthermore, as to this particular subject matter, the court found that Dr. Trovato's testimony would be inappropriate. [E.575-76].

Maryland Rule 5-702 governs testimony by expert witnesses. It provides as follows:

> "Expert testimony may be admitted, in the form of an opinion or otherwise, if the court determines that the testimony will assist the trier of fact to understand the evidence or to determine a fact in issue. In making that determination, the court shall determine (1) whether the witness is qualified as an expert by knowledge, skill, experience, training, or education, (2) the appropriateness of the expert testimony on the particular subject, and (3) whether a sufficient factual basis exists to support the expert testimony"

The lower court ruled that Dr. Trovato lacked the necessary experience and training to qualify as an expert to discuss whether Dr. Shannon breached his duty to obtain informed consent from Mr. Fusco by disclosing certain material risks (which, as discussed above, were never identified by Dr. Trovato in discovery). [E.575-580]. The trial court's ruling in this regard is well-supported by the record below and is consistent with Maryland statutory and case law.

First, Dr. Trovato is **a pharmacist, not a physician.** The education and training that a physician undergoes is far different from that of a pharmacist. Dr. Trovato did not complete a medical residency, fellowship, and specialized training, as Dr. Shannon did, to become triple-board certified in internal medicine, ***27** hemotology, and oncology. [E.140, 1391-92]. Dr. Trovato was not trained to evaluate, diagnose and treat oncologic patients in a clinical setting like Dr. Shannon. Id. Furthermore, under Sard and its progeny, the proper test for measuring the physician's duty to disclose risk information is whether such data will be material to the patient's decision. A material risk is defined as "one which a physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether to submit to a particular medical procedure." *See Sard v. Hardy*, 281 Md. 432, 444, 379 A.2d 1014, 1022 (1977). In summary, the definition of material risk mandates consideration of what a physician knows or should know, not what a pharmacist knows or should know.

Second, and most significantly, Dr. Trovato is not licensed to practice medicine. [E.139]. This is a pivotal point because recommending a treatment course - *and obtaining informed consent for that treatment course* - constitutes the practice of medicine. Dr. Trovato does not do this in his profession - and he cannot do this under Maryland law as that would constitute an unauthorized practice of medicine. The unauthorized practice of medicine constitutes grounds for discipline in Maryland under Health Occupation Title, § 14-404(a)(18). See Md. Code Ann. (1981, 2009 Repl.Vol.), Health Occ. Art. (HO) § 14-404(a)(2), (3) and (18). If one is prohibited, by law, from practicing medicine, it goes without saying that he/she should be prohibited from offering opinions in a medical malpractice trial that a practicing physician breached his duty to sufficiently inform the patient of all material risks, benefits and alternatives to a proposed ***28** treatment so as obtain informed consent.

It is well recognized that lack of informed consent claims sound in negligence, thereby triggering the concept of "duty." *See e.g., Dingle v. Belin*, 358 Md. 354, 368, 749 A.2d 157, 164-65 (2000)(expressly stating that "we recognized, as a separate *negligence-based* (rather than battery-based) cause of action, the performance of a medical procedure by a physician without the informed consent of the patient"). Accordingly, a physician has a "duty" to impart certain information to a patient. As the *Sard* Court explained, "the doctrine of informed consent imposes on a physician, before he subjects his patient to medical treatment, the **duty** to explain the procedure to the patient and to warn him of any **material risks** or dangers inherent in or collateral to the therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to undergo such treatment." *Id.* at 439, 379 A.2d at 1020 (emphasis added). *Dr. Trovato is not authorized to do what Dr. Shannon did in this case, i.e., obtain Mr. Fusco's informed consent.* It makes no sense, neither logically nor under the statutes which guide the practice of medicine in this State, to permit a person who cannot be held to the same "duty" as a licensed practicing physician, to testify about that "duty" in a court of law. If the law imposes a duty on a physician, it necessarily follows that the witnesses permitted to opine on that duty, should be physicians, at a bare minimum.

Given that Dr. Trovato is not licensed to practice medicine, it is no surprise, then, that he *cannot prescribe medications*, including the Amifostine at issue in ***29** this case. [E.140]. He has never sat down with a patient and written a prescription for medication at any time. [E.143]. Given that Dr. Trovato is not licensed to practice medicine, naturally, **he's never himself obtained a patient's consent to treatment, and in particular, to the use of Amifostine.** [E.157, 160]. It is no surprise then that Dr. Trovato did not understand the term "material risks." [E.143].

Despite the above-referenced lack of qualifications, Appellants attempt to seek cover in this Court's recent case, *Wantz v. Afzal*, 197 Md. App. 675, 14 A.3d 1244 (2011). The disputed testimony in the Wantz case involved opinions by a neurosurgeon as to causation, i.e., the outcome a patient would have had if she been immobilized prior to the spinal fusion. Id. at 684, 14 A.3d at 1249-50. The neurosurgeon was excluded on the basis that he hadn't actually performed the type of spinal fusion at issue. This Court correctly pointed out that the lower court's conclusion failed to consider the purpose for which the neurosurgeon's testimony was offered: "the thrust of [the neurosurgeon's] testimony was that 'immobilization and immediate surgery, as soon as the fractures were discovered, would have prevented Mrs. Reynolds' paralysis... [and] had she not been paralyzed at the time of surgery, her chances of success were good, but because she was, the fusion was unlikely to take. *Id.* Therefore, the neurosurgeon's inexperience with performing the spinal fusion surgery should not disqualify him from offering testimony regarding the pre-operative cause of paralysis. *Id.* at 685, 688.

***30** Clearly, the Wantz opinion is distinguishable from the case at hand for a myriad of reasons. First, the expert testimony involved issues of causation, not elements of "duty" as exist in this case. In a medical malpractice action, the distinction between duty and causation is significant in terms of the qualifications of the expert so opining. For example, the Health Care Malpractice Claims Act protects defendant-healthcare providers from having persons who lack similar background, education and training from rendering opinions against them as to violations in standard of care. See Cts. & Jud. Pro. Art., §3-02-04. Although Section 3-02-04 has not been applied to lack of informed consent claims, per se, there are arguably certain policy goals that would be defeated if courts were to permit non-physicians come into court and testify about a physician's "duty" to inform patients.

Along those lines, *Wantz* is further distinguishable because the neurosurgeon in that case was found to have had sufficiently similar experience with spinal fusions so as to be qualified to render opinions regarding the patient's outcome. In the case sub judice, however, it would be *impossible* for Dr. Trovanto to have sufficiently similar experience given that he is *not a physician* - he is not **licensed to practice medicine** - and not only has he **not obtained informed** consent for patients undergoing a proposed treatment course, he is *forbidden* from doing so by Maryland statute. In short, the *Wantz* decision does not provide Appellants the life ring buoy that they contend it does.

For the reasons discussed supra, the trial court ruled that Dr. Trovato's ***31** area of expertise was not germane to the issues in this case. His expertise is "not in the complete treatment plan... *he only deals with the medications."* [E.575-76]. The court additionally noted that "he's never given an informed consent. He's not trained in informed consent. And he, quite frankly, he is very limited in what he does with patients. And the final call is not his. It is always the doctor. That's the way the medical system is set up." Id. Accordingly, the lower court ruled that Dr. Trovato, as a pharmacist, **"does not have the ability to give the full demarcation as to what is involved in informed consent."** *Id.*

As this Court is aware, the admissibility of expert testimony is an area which the trial court is given broad discretion, and it rarely constitutes grounds for reversal. *See Globe Sec. Systems Co. v. Sterling*, 79 Md. App. 303, 308, 556 A.2d 731 (1989). In fact, so broad is the trial court's discretion that it will not be disturbed on appeal unless it has been shown to be manifestly erroneous. *See Troja v. Black & Decker Mfg. Co.*, 62 Md. App. 101, 110, 488 A.2d 516, 520 (1985). Precluding Dr. Trovato from rendering opinions at trial as to Dr. Shannon's duty to advise Mr. Fusco of certain material risks to constitute informed consent was proper and well-within the trial court's broad discretion. In this regard, it is significant that the lower court's ruling is consistent with Maryland statutory law given that Dr. Trovato is not even authorized to obtain informed consent of a patient. *See* Md. Code, Health Occ. Art. § 14-404(a)(2), (3) and (18). The lower court's ruling is also consistent with Maryland case law which defines a material risk as one which a "physician knows or ought to know" ***32** would be significant to a patient, not

one that a pharmacist knows or ought to know. Finally, the lower court's ruling is in accordance with Maryland Rule 5-702 in that Dr. Trovato does not meet the factors outlined therein to qualify for admissibility. *See* Md. Rule 5-702. Thus, the court's ruling was not manifestly erroneous and should be affirmed on appeal.

C. The Trial court properly granted Appellants' motions in Limine pertaining to the Drug's Package Insert and Reference to FDA approved uses of Amifsotine

The lower court's rulings which (a) precluded the use of a drug package insert from Amifostine, and (b) precluded discussion of whether or not Amifostine was FDA approved for use in prostate cancer patients were entirely proper under these factual circumstances. This Court will recall that this "evidence" formed the basis for Dr. Trovato's testimony that the use of Amifostine was inappropriate. There was never any link made between this evidence and the lack of informed consent claim, to wit: that these issues equated to material risks. That said, relevancy was not the only basis to exclude this evidence.

1. The package insert's precautionary statement that there had been limited clinical trials involving elderly patients was properly excluded by the trial court.

Despite *never* having elicited testimony that Dr. Shannon breached his duty to obtain informed consent by failing to disclose that the drug had limited clinical testing [5] in the **elderly** (a statement taken from the drug package insert), Appellants ***33** hoped to introduce evidence at trial that the package insert contained a note cautioning that the drug had not been tested in the **elderly**. [6] There were multiple problems with the package insert. First, it post-dated the drug that was used by Mr. Fusco. [E.540]. Second, it was from a different manufacturer than the manufacturer who was responsible for the Amifostine utilized by Mr. Fusco. *Id.* Third, there was no expert testimony that the package insert was authoritative or reasonably reliable within the field. Fourth, there was no expert testimony to support or establish that a precautionary notification about the limited testing of Amifostine in **elderly** patients was equivalent to a "material risk" to the use of the drug, such that Dr. Shannon had a duty to disclose this "material risk" to Mr. Fusco.

Had Appellants presented a package insert from the appropriate manufacture and from the appropriate time period, and had Appellants produced a *qualified* expert who offered opinions, timely in discovery, that the lack of testing equated to a material risk, and had Appellants produced a qualified expert who offered opinions, timely in discovery, that Dr. Shannon breached his duty to obtain informed consent by failing to disclose this information about limited testing on the **elderly** -as espoused in the package insert which this *qualified* expert would ***34** also testify was reasonably reliable - then certainly Appellants may have been entitled to elicit such testimony. Given that Appellants possessed **none** of the above factors, the trial court's ruling precluding the use of the package insert (and the information contained therein) was entirely appropriate. Appellants want to blame the trial court for a "pattern of **abuses**" and "flawed rulings" when, in fact, the rulings could have been easily sidestepped had Appellants themselves adduced the appropriate evidence in the appropriate manner at the appropriate time. The trial court's ruling was not a knee-jerk ad hoc reaction to the package insert; it was a ruling well supported by the Maryland Rules and case law on multiple different fronts.

Nevertheless, Appellants' counsel disregarded the lower court's ruling which instructed that *no mention* of the warnings on the package insert about **elderly** patients be made. [E.911]. Several times, in opening statements, Appellants' counsel mentioned that the medication "had a warning" that it had not been tested for use in the **elderly** and further, that Mr. Fusco was not advised of that warning.

"this medication... has a warning. This should not be used in **elderly** patients. This medication has not been tested in **elderly** patient, amifostine. Be very careful if you're going to use this medication in **elderly** patients. And neither Dr. Shombert nor Dr. Shannon told Michael or Anthony Fusco that fact. Neither of them told him what the medication said about use with **elderly** patients..." [E.924]

> "Was he advised that it shouldn't be used in **elderly** patients and you have to be very cautious because we don't know the effects of this in **elderly** patients?"

***35** [E.929]

"Did he ever tell you... that there are precautions saying it hasn't been tested in **elderly** patients? No, he never told us that... Let me tell you this. The fact...that there are strong precautions for use in **elderly** patients is not disputed.... Everybody agrees that he was never advised that this mediation has not been properly tested for use in **elderly** patients... Never told that." [E.934].

Thus, in spite of the court's ruling precluding counsel from utilizing or mentioning the package insert in opening statement, Appellants' counsel, within minutes of that ruling, did precisely that. Nevertheless, Appellants' counsel boasts in his Brief to this Court that he "did not mention the FDA approved use of Amifostine or show the exhibit [package insert] in opening statement." See App. Brief, pg. 27. Noticeably absent from this assertion is any reference to the fact that, in violation of the court's ruling, he mentioned the package insert and **elderly** warning multiple times in opening statements. Accordingly, the "extreme, unwarranted sensitivity on the part of the court," that Appellants' counsel alleges occurred below, was for good reason: the lower court instructed him not to mention in opening statement precisely that which he mentioned in opening statement. [E.933-936].

2. Evidence regarding the lack of FDA approval specific to prostate cancer was properly excluded by the trial court.

Similarly, despite *never* having elicited testimony that Dr. Shannon had a duty to disclose that the drug was being used in an off-label manner for prostate cancer patients, Appellants wanted to introduce evidence that the FDA approval of ***36** Amifostine was limited to kidney, bladder, and neck cancer, and not prostate cancer; in other words, the use of the drug in prostate cancer patients was, from the FDA standpoint, an off-label use. Appellants failed to adduce any evidence, however, that an off-label use of the drug equated to a material risk of the drug, for which Dr. Shannon had a duty to disclose. [7]

The case of *Waldt v. University of Maryland Medical System*, 411 Md. 207, 983 A.2d 112 (2009) is analogous and controlling. There, the trial court received a proffer from plaintiffs' expert that the device (a neuroform stent) was not approved by the FDA for use on Mrs. Wald's type of aneurysm. The trial court concluded that such evidence was a not a proffer of an inherent risk to the procedure that Mrs. Waldt underwent; rather, it was a proffer of expert testimony that the procedure was contraindicated for Mrs. Waldt, and therefore should not have been performed on her. *Id.* at 235-36. The Court of Appeals agreed and stated that this "expert testimony would be relevant to an ordinary negligence claim, i.e., that the doctors breached the standard of care in their treatment of Mrs. Waldt by performing a contraindicated procedure on her. It is not relevant to an informed consent claim." *Id.* at 236. In short, that aspect of the expert's proffered opinions was ruled irrelevant and inadmissible. *Id.* Because the witness had no other basis to support his opinions on lack of informed consent and further, had limited experience with the procedure, the witness was precluded from testifying. ***37** Id. at 237. The Court of Appeals upheld these rulings by the lower court. *Id.*

Like the Waldt case, the testimony concerning off-label use of Amifostine goes to just that: its use. Such evidence is not relevant to an informed consent claim. Furthermore, in the case sub judice, Dr. Trovato was precluded from testifying prior to trial; yet, at trial, Appellants still wanted to introduce evidence of the fact that the FDA had not formally approved the drug in prostate cancer cases - despite the lack of expert testimony to establish relevance or reliability. The trial judge correctly ruled that such statements would confuse the jury given that there was no testimony to link it to any component of informed consent. Consistent with the Waldt ruling, the fact that a drug is approved (or not) by the FDA begs the question as to whether it was a breach in the standard of care to use the drug, not whether the physician failed to adequately inform the patient on the material risks, benefits and alternatives to the proposed course of treatment. Furthermore, Appellants offered no witness who could equate the fact that the FDA had not yet approved the drug for prostate cancer to a material risk to using the drug. For these reasons,

the trial court was entirely correct to refuse to allow Appellants' counsel to discuss the FDA approval issue with the jury in opening statements. [E.602].

In summary, the lower court's evidentiary rulings pertaining to the FDA approval, the package insert, and the clinical trials were proper and well within the lower court's broad discretion. There was no testimony to support that these factors were "material risks" to the use of Amifostine. Certainly, these rulings ***38** were not manifestly erroneous - and thus, the court's discretion should not be disturbed on appeal.

D. Conclusion: The Trial Court's Rulings were Proper and Well Within its Broad Discretion. Judgment Be Affirmed.

In conclusion, the trial court's preclusion of Dr. Trovato and its evidentiary rulings below were proper and well within its broad discretion. As a result, the rulings below should be upheld and the judgment in favor of Dr. Shannon should be affirmed.

ARGUMENT AS TO ISSUES ON CROSS-APPEAL

Appellees maintain that the facts adduced in discovery mandated an entry of summary judgment on their behalf prior to commencement of trial. [E.356, E.534]. Additionally, Appellees moved for judgment at the close of Appellants' case [E.1259-1268] and at the close of evidence. [E.1543-1551]. Given Appellants' failure to establish a *prima facie* case of lack of informed consent, judgment should have been entered in Appellees' favor at any of those junctures.

A. Standared of Review

Summary judgment is appropriate when, after viewing the motion and the response in favor of the non moving party, there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *See Messing v. Bank of America, N.A.*, 143 Md. App. 1, 10, 792 A.2d 312, 317-18 (2002); Md. Rule 2-501(e). When reviewing a trial court's grant of summary judgment, the appellate court's standard of review "is whether the trial court was legally ***39** correct." *Heat & Power Corp. v. Air Prods. & Chems., Inc.*, 320 Md. 584, 591, 578 A.2d 1202 (1990). When considering the propriety of a lower court's grant of a motion for summary judgment, appellate courts adhere to a de novo standard of review. *See Mamsi Life & Health Ins. Co. v. Callaway*, 375 Md. 261, 825 A.2d 995 (2003). Given the paramount importance of disputed facts in the summary judgment process, when sufficient grounds for summary judgment have been set forth by the moving party, "the party opposing the motion must show with 'some precision' that there is a genuine dispute as to material fact." *Bond v. NIBCO, Inc.*, 96 Md. App. 127, 135, 623 A.2d 731 (1993) (quoting *Seaboard Sur. Co. v. Richard F. Kline, Inc.*, 91 Md. App. 236, 243, 603 A.2d 1357 (1992))(emphasis omitted). The opposing party "cannot rely on formal denials or general allegations." *Bond*, 96 Md. App. at 135, 623 A.2d 731. Rather, the opposing party must produce evidence upon which the jury could reasonably find in his favor.

Even assuming the truth of the evidence adduced by Appellants, Appellants could not sustain a legal cause of action for lack of informed consent given that Appellants put forth no testimony concerning the material risks to Amifostine that were required to be disclosed. Additionally, even assuming Appellants were premitted introduce the evidence pertaining to the package insert, the lack of FDA approval, etc., *none* of this evidence would cure the dispositve defect in Appellants' case given that there was no expert testimony to equate those issues to "material risks" to the use of Amifostine.

***40** Trial courts "should not be reluctant to grant a motion for summary judgment in an appropriate case... a motion for summary judgment, although not a substitute for trial, is nevertheless not disfavored. A proper summary judgment motion is to be granted unless the parties truly dispute a material fact, i.e., the evidence is such that a fair minded jury could return a verdict for the nonmovant." *Bond v. NIBCO, Inc.*, 96 Md. App. 127, 134-35, 623 A.2d 731, 735 (1993) (quoting *Seaboard Surety Co. v. Richard F. Kline, Inc.*, 91 Md. App. 236, 244, 603 A.2d 1357 (1992) (internal citations omitted) (emphasis in original)). As has been established herein, even if you assume the facts in the light most favorable to Appellants, Appellants failed to adduce any evidence of material risks that were not disclosed to Mr. Fusco. Appellants' claims in this regard were legally deficient.

Accordingly, this is precisely the "appropriate case" for which a grant of summary judgment was proper as a matter of law. The trial court's denial of summary judgment was erroneous, and should this matter be reversed on appeal for any of the reasons cited above, this Court should remand with an order to enter judgment in Appellees favor.

Likewise, in reviewing the denial of a motion for judgment, the appellate courts utilize a de novo standard of review. Specifically, appellate courts consider whether, on the evidence presented, a reasonable fact-finder could find the elements of the cause of action by a preponderance of the evidence. *See University of Maryland Medical System v. Gholston*, 203 Md. App. 321, 329, 37 A.3d 1074 (2012). Given that Appellants did not adduce any evidence that Dr. ***41** Shannon failed to inform Mr. Fusco of material risks to Amifostine, no reasonable finder of fact could conclude that the elements of lack of informed consent had been established; thus, Appellees were entitled to judgment in their favor.

Therefore, under either mechanism (summary judgment or judgment), the trial court's failure to enter judgment on behalf of Appellees was erroneous.

B. Evidence as to "Material Risks" are necessary to establish a Prima Facie case of Lack of Informed Consent.

Informed consent, as applied today, was first established in *Sard v. Hardy*, 281 Md. 432, 379 A.2d 1014 (1977). In Sard, the Court of Appeals stated that "the doctrine of informed consent imposes on a physician, before he subjects his patient to medical treatment, the duty to explain the procedure to the patient and to warn him of any material risks or dangers inherent in or collateral to the therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to undergo such treatment." *Id.* at 439, 379 A.2d at 1020 (emphasis added). Furthermore, "the scope of the physician's duty to inform is to be measured by the materiality of information to the decision of the patient." *Id.* at 444, 379 A.2d at 1022.

As with any negligence action, there exists a duty of care and a breach of that care. In an informed consent case, "the proper test for measuring the physician's duty to disclose risk information is whether such data will be **material** to the patient's decision... a **material risk** is one which a physician knows or ought to know would be significant to a reasonable person in the patient's position ***42** in deciding whether or not to submit to a particular medical treatment or procedure." *Sard*, 281 Md. at 443-444, 379 A.2d at 1022.

Cases subsequent to Sard have continued to define the physician's duty in informed consent cases to that which a **physician** knows or ought to know would be significant to a reaonable patient. See McQuitty, 410 Md. at 21, 976 A.2d at 1032 (explaining that the "materiality test" was the best measure of a healthcare provider's duty to provide information); Zeller v. Greater Baltimore Med. Center, 67 Md. App. 75, 84, 506 A.2d 646, 651 (1986). Thus, "material risks" is the fundamental question in establishing duty in an informed consent claim, the scope of which is defined as **that which a physician knows or ought to know.**

Furthermore, the Court of Appeals has made clear "**expert testimony is necessary to establish the material risks** and other pertinent information regarding the treatment or procedure." *Waldt*, 411 Md. at 232, 983 A.2d at 127. The determination of what constitutes a "material risks" should not be left to the jury. Maryland law affirms that a physician is not obligated to disclose risks that are insiginficant or infintesimal.[8] *See McQuitty*, 410 Md. at 12, 976 A.2d at 1032 (stating that a healthcare provider is not burdened with the duty of divulging all risks, but only those which are material to the intelligent decision of a reasonably prudent patient)(internal citations omitted). Therefore, without expert testimony as to what constitutes "material risks," the jury would be left ot speculate as to ***43** what may be significant or not.

Appellants produced no expert testimony on the issue of material risks to Amifostine.[9] No expert testified that TENS was a material risk Amifostine; no expert testified that Stevens Johnson Syndrome was a material risk to Amifostine; no expert testified that off-label use was a material risk to Amifostine; no expert testified that limited clinical trials on prostate cancer

or **eldery** patients was a material risk to Amifostine. On every level conceivable, Appellants' failed to establish a *prima facie* case of lack of informed consent.

Incidentally, this Court need not go into great detail as to the type of witness who would qualify to testify about material risks in this case, i.e., whether that physician needs to be similarly board certified, or have used the same drug, or have proposed the same treatment. Indeed, this case is far more simple: Dr. Trovato is a pharmacist, not a physician; therefore, he does not qualify to testify as to that which constitutes "material risks" to a proposed treatment. Stated ***44** differently, a pharmacist should not be permitted to render opinions as to the duty of care imposed upon a physician.

Given that Appellants had no *qualified* expert witness to testify as to the material risks to the use of Amifostine, Appellants failed to adduce evidence to establish duty, or breach thereof, as it pertains to informed consent. That notwithstanding, even if this Court allows a pharmacist to testify as to the duty of care for a physician in obtaining informed consent, Dr. Trovato failed to offer any opinions as what constituted a "material risk" of Amifostine requiring disclosure by Dr. Shannon in order to satisfy the doctrine of informed consent. Dr. Trovato never rendered those opinions in deposition, nor did he render those opinions in his *de bene esse* videotaped testimony. The lack of evidence on "material risks" was a dispostive gap in Appellants' case warranting both summary judgment prior to trial and judgment during trial.

As it relates to summary judgment, taking the evidence in the light most favorable to the Appellants, Appellants did not adduce any evidence that Dr. Shannon failed to inform Mr. Fusco of a material risk to Amifostine; accordingly, Dr. Shannon was entitled to judgment as a matter of law. Likewise, as it relates to Appellees' motion for judgment, no reasonable fact-finder could find the elements of the cause of action for lack of informed consent, given that Appellants case was void of any evidence that Dr. Shannon failed to advise of a material risks. As a result, Appellees were also entitled to judgment at the close of Appellants' case and/or the close fo the evidnece.

*45 CONCLUSION

The trial court properly granted of Appellees' Motion in Limine and properly precluded Appellant's pharmacist's testimony. Furthermore, the trial court made appropriate evidentiary rulings concerning the FDA-approval evidence, package inserts and reference to clinical trials. For these reasons, the judgment in favor of Appellees should be affirmed by this Court.

With respect to the issue on cross-appeal, the trial court erred in denying summary judgment and/or judgment on behalf of Appellees given that Appellants case was void of any evidence that Dr. Shannon failed to disclose a material risk to Mr. Fusco. Thus, should this matter be remanded due to some error below, this Court should remand with instructions to enter judgment in favor of Appellees.

Appendix not available.

Footnotes

1 SJS and TENS are skin conditions in which cell death causes the dermis to separate from the epidermis. [E.1145-45]. The majority of causes are idiopathic, but the known causes are allergic reactions or hypersensitivities to medications, infections and in rare cases, cancer.

2 The jury was unable to reach a unanimous conclusion as to question (1)-pertaining to whether Dr. Shannon advised Mr. Fusco of the material risks, benefits and alternatives to the Amifostine drug. The jury provided a note to the lower court indicating that while they could not reach a unanimous conclusion to question (1), they were unanimous as to question (2) which would conclude their deliberations. [E.1711]. For this reason, the trial court elected to take the verdict. It is noteworthy that Appellants did not move for a mistrial on this basis; Appellants did not file a motion for new trial on this basis; and Appellants did not appeal this issue to this Court. Accordingly, the lower court's decision to take the verdict is not an issue before this Court.

3 Curiously, Appellants' mischaracterize Dr. Trovato as a “pharmacologist” rather than his true profession as a “pharmacist” in their Brief. Dr. Trovato is a pharmacist. [E.136]. The training programs and licensing programs for pharmacology and pharmacy are different and distinct.

4 Appellees noted their objection to the “proffer” to the extent that it included new opinions not previously disclosed in discovery. [E.562-63].

5 Appellants' desire to adduce evidence at trial about the limited number of clinical trials on the **elderly** and on prostate cancer patients was properly excluded for the same reasons discussed in subsections (1) and (2) infra; accordingly, the arguments will not be repeated.

6 Appellants dramatize that which is stated in the package insert, so as to imply that the insert stated that use in **elderly** patients was contraindicated. It was not a contraindication; rather, it was a precautionary note which advised that the drug had not been tested extensively in the **elderly** population.

7 Nevertheless, Dr. Shannon testified in deposition that it would have been his custom to mention that the drug was being used off-label.

8 Speaking of infinitesimal, the undisputed testimony in this case established that the risk of SJS or TENS from Amifostine is between 6-9 cases per 10,000, for a statistical rate of 0.06 to 0.09. [E.1547-48].

9 In response to the motions for judgment, Appellants claimed that Dr. Shannon testified as to material risks and therefore, they met the obligation to have expert testimony on material risks. [E.1261] Naturally, as the defendant-physician in the case, Dr. Shannon testified about the material risks that he discussed with Mr. Fusco. Dr. Shannon never testified, however, that there were certain material risks to Amifostine that he failed to disclose. Quite to the contrary, the only expert testimony adduced both in discovery and in trial as to “material risks” established that Dr. Shannon disclosed all necessary material risks to Amifostine, i.e. he complied with the duty of care for informed consent. Appellants cannot meet their burden of proof regarding a breach of a duty of care in an informed consent case by eliciting testimony from the defendant-physician that he complied with the duty to obtain informed consent. Such a position is nonsensical and, if plaintiffs are permitted to so easily defeat motions for summary judgment and motions for judgment in this manner, the duty to mount a prima facie case becomes void.

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